K012928

OCT - 9 2001

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Formerly American Biosystems, Inc.

13 August 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Submitter: Eric J. Larson
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Advanced Respiratory
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Contact person: Eric J. Larson

Name of Device: Modified Vest™ Airway Clearance System

Classification: Powered Percussor, Class II

Predicate Device: ABI Vest™ Airway Clearance System, 510(K) number: K993629

Description of Device:

The Advanced Respiratory modified Vest™ Airway Clearance System is a high-frequency chest wall oscillator for enhancing the mobilization of bronchial secretions. The device is designed for use in applications where patients are unable to manually operate the device output functions, e.g. organ donor procurement centers. The primary components of the Advanced Respiratory modified Vest™ Airway Clearance System include an air-pulse generator, an inflatable vest and connecting tubing. Oscillating positive pressure air pulses are applied to the vest by the air-pulse generator. The resulting pressure pulses cause the vest to inflate and deflate against the chest of the donor patient creating high-frequency chest wall oscillation that results in the mobilization of bronchial secretions. The air output pulses are set at a fixed frequency (13 Hertz) and pressure (equal to a dial setting of 6 on the predicate device).

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:
The intended use of the modified Vest™ Airway Clearance System is to promote airway clearance or improve bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. The indications typically follow the Clinical Practice Guideline published by the American Association for Respiratory Care (AARC) 1991. In addition, the device is also indicated for the purpose of collecting mucus for diagnostic evaluation.

Comparison of Technological Characteristics:
The modified Vest™ Airway Clearance System is substantially equivalent to the previously cleared ABI Vest™ Airway Clearance System (a.k.a. ThAIRapy® Vest System) (K993629), which is intended to promote airway clearance or improve bronchial drainage by enhancing the mobilization of bronchial secretions when external manipulation of the thorax is the physician's choice of treatment. The reason for this submission is to modify the predicate device to set the frequency and pressure at optimal values and add software that controls the therapy time duration and pause duration between therapy sessions.

Performance Testing:
The modifications have been compared to safety and effectiveness previously established by the market-cleared Vest System predecessor. A paired t-test on 15 vest pressure comparisons using all 5 of the standard size vests depicts that the modified Vest system and predicate Vest system are equivalent when the predecessor controls are adjusted to the set parameters of the modified vest system. The calculated t-value of .34 for the 15 comparisons is well within the t critical value for statistical equivalence with an alpha of .05 of ± 2.145.

The modified Vest System is listed to U.L. 544, "Standard for Safety" for Medical and Dental Equipment, the same standard as the predecessor is listed.

The modified Vest system also passed FCC Part 15 testing and European Standard EN 60601-1-2 testing

The overall dimensions or weight of the modified device is the same as the predicate

The vest components that are used with the modified Vest System is the same as the vests used with the predicate device

Conclusion:
Comparison testing of the modified model to the predicate Vest System demonstrates that the performance and safety is equivalent to the predicate with the controls adjusted to the set parameters of the modified system, i.e., frequency at 6 Hz and pressure to dial setting of 6.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2001

Advanced Respiratory
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K012928
ABI Vest™ Airway Clearance System
Regulation Number: 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II (two)
Product Code: 73 BYI
Dated: September 24, 2001
Received: September 25, 2001

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known) K012928

Device Name: Modified Vest™ Airway Clearance System

Indications for use:

The intended use of the Advanced Respiratory modified Vest™ Airway Clearance System is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy[1] (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. The Advanced Respiratory modified Vest™ Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

1. Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC clinical practice guideline: postural drainage therapy. Respiratory Care 1991; 36: 1418 – 1426.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012928